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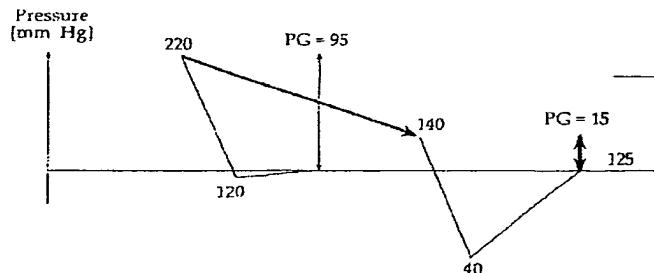
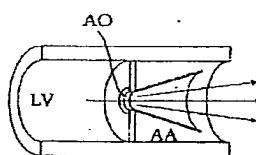
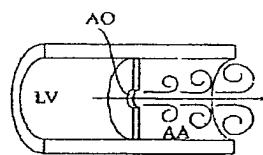
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(54) Title: FLUID FLOW PROSTHETIC DEVICE



(57) Abstract: Apparatus is provided, including a prosthetic device, having a single flow field therethrough, adapted for implantation in a subject, and shaped so as to define a fluid inlet and a diverging section, distal to the fluid inlet. The prosthetic device includes a plurality of axially-extending struts (112) which extend along at least a portion of the diverging section and diverge outwardly, such that distal ends of the struts are spaced further from one another than proximal ends of the struts throughout a cardiac cycle of the subject. The diverging section includes a diverging envelope (111), coupled to the struts, which is adapted to assume an open position thereof during systole, permitting blood flow through the device, and which is adapted to collapse to a closed position thereof during diastole, inhibiting blood flow through the device.

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FLUID FLOW PROSTHETIC DEVICE

CROSS-REFERENCES TO RELATED APPLICATIONS

The present patent application claims the benefit of, and is a continuation-in-part of, US Patent Application 11/024,908 to Schwammenthal et al., entitled, 5 "Fluid flow prosthetic device," which is assigned to the assignee of the present patent application and is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates in general to implantable medical devices, and specifically to implantable prosthetic devices. Embodiments of the present 10 invention are particularly useful in prosthetic devices implantable by transarterial delivery for the treatment of aortic stenosis in the aortic valve of a patient's heart, and these embodiments are therefore described below with respect to such applications. It will be appreciated, however, that embodiments of the invention could also be used for other treatments, such as but not limited to, aortic 15 regurgitation, mixed aortic stenosis and regurgitation, other valvular lesions, or the treatment of obstructed blood vessels or other body passageways, such as the urinary tract or gastrointestinal tract. Embodiments of the invention also relate to methods for implanting such prosthetic devices.

BACKGROUND OF THE INVENTION

20 Aortic stenosis is the obstruction of outflow from the left ventricular chamber into the aorta caused by a restricted opening of the aortic valve during left ventricular contraction and ejection. The diminished aortic valve opening area (from normally more than 3 cm² in an averaged sized adult to less than 0.5 cm² in severe cases) results in a significant pressure drop across the valve, and normal 25 cardiac output and aortic pressure can only be maintained at the expense of increased left ventricular systolic pressure. The high intracavitory pressure which has to be generated by the left ventricular chamber results in increased wall tension and myocardial oxygen demand. Adaptive processes such as hypertrophy (compensatory increase in muscle mass) allow the heart to withstand this

increased pressure load for some time, but ultimately, pump failure is considered generally inevitable.

In the majority of cases, aortic stenosis is caused by progressive fibrous and calcified degeneration of an originally normal valve, a process which is 5 favored by hyperlipoproteinemia, arterial hypertension, and aging (acquired calcified aortic stenosis). The average survival of a patient with severe aortic stenosis and shortness of breath is less than two years. Since death may occur suddenly in a substantial portion of cases, some investigators recommend preventive surgery even in asymptomatic patients, provided they are good surgical 10 candidates.

Surgical results in the selected group of patients with isolated aortic stenosis are reasonable. Operative mortality in such patients is about 5%. However, most individuals with significant aortic stenosis are in their seventies and eighties. These patients usually have multiple comorbid risk factors, such as 15 coronary artery disease, cerebrovascular disease, generalized atherosclerosis, renal failure, or diabetes. Consequently, surgical mortality and morbidity are substantial. Moreover, if the calcified aortic valve is replaced by a mechanical prosthesis, anticoagulation is mandatory to reduce thromboembolic complications, which exposes the patient to an increased risk of serious bleeding, particularly 20 with increasing age. Implantation of biological prostheses is therefore usually preferred in the elderly, but surgically implanted biological valves may have a suboptimal hemodynamic profile, because the suture ring on which the valve needs to be mounted reduces the space available for the valve itself. This poses a 25 particular problem in women, where bioprostheses of a smaller size (which have to be used because of the smaller cardiac dimensions) may result in significant residual outflow obstruction.

Because of the significant risk of elderly patients undergoing open-heart surgery on cardiopulmonary bypass, which includes death, disabling stroke, respiratory and renal complications, dilatation of the narrowed valve using 30 balloon-catheters was hoped to provide an alternative to surgery. Unfortunately, because immediate results of the balloon dilatation are suboptimal, and recoil of the stenosis reoccurs within weeks and months in virtually all patients, outcome is

as poor as in patients who do not undergo surgery. Balloon-dilatation is therefore considered only justified in patients with a clear contraindication to surgery or – in rare cases - as a “bridging procedure”.

Recently, in analogy to the use of stents in coronary arteries, it has been
5 proposed to use valved stents in order to achieve a sufficiently large valve area
and avoid elastic recoil and restenosis. Spencer et al (U.S. Patent 6,730,118),
Andersen et al (U.S. Patent 5,840,081) and Gabbay (PN 4,759,758) all describe a
valved stent of certain designs that are intended for transarterial deployment.
Cribier et al describes, in WO 98/29057, a collapsible stent which has a valve
10 attached to it by circumferential suturing. The mesh/valve system is deployed via
an inflatable balloon. In 1992, Andersen et al. reported their experience with a
foldable porcine aortic valve sutured in an expandable stainless-steel stent. The
valved stent was mounted on an 18–22 mm balloon-catheter front-loaded in a
16F Mullins long sheath and implanted in the pulmonary position, completely
15 displacing the pulmonary cusps (or leaflets), which were pressed between stent
and pulmonary artery wall with full deployment of the stent. However, this
approach could result in coronary artery occlusion when undertaken in the aortic
position, which would be fatal to the patient.

Even when the stent is not deployed across the full area of the aortic
20 annulus, atheromatous deposits on the ventricular side of the aortic cusps (or
leaflets) may be pushed against the ostia of the coronary arteries causing severe
coronary obstruction or embolization. Severe distention of a heavily calcified
aortic valve to allow deployment of a sizeable stent may also cause embolization
25 of calcium deposits from the valve or a tear in the valve resulting in significant
aortic regurgitation. Furthermore, a large stent-valve may also interfere with
surrounding structures such as the anterior mitral leaflet (causing damage to it or
impairing its function), and if protruding into the left ventricular outflow tract, the
basal ventricular septum, which is usually hypertrophied in significant aortic
30 stenosis.

The following references describe prosthetic valves, and are considered of
interest:

US Patent 5,344,442 to Deac

US Patent 5,908,451 to Yeo

US Patent 6,312,465 to Griffin et al.

US Patent Application Publication 2004/0260389 to Case et al.

PCT Patent Publication 2005/002466 to Schwammthal et al. (which is
5 assigned to the assignee of the present patent application).

It is noted that Figs. 1-3 of the Yeo patent show a valve including a pair of leaflets, which, when in the open position, create three blood flow fields through the valve (a central channel and two side channels). Similarly, Figs. 1A, 1B, 6, and 7 of the Griffin patent show a valve including a pair of leaflets, which, when 10 in the open position, create three blood flow fields through the valve (a central channel and two side channels).

The following references are also considered of interest:

US Patent 5,354,330, US Patent 4,078,268, US Patent 4,846,830, US
15 Patent 5,108,425, US Patent 6,299,638, US Patent 6,171,335, US Patent
6,338,740, US Patent 6,761,736, US Patent Application Publication
2004/0186563, US Patent Application Publication 2004/0215333, and US Patent
Application Publication 2005/0015112.

The following articles may be of interest:

Heinrich RS et al., Ann Biomed Eng. 1996 Nov-Dec;24(6):685-94.
20 Experimental analysis of fluid mechanical energy losses in aortic valve stenosis:
importance of pressure recovery.

Heinrich RS et al., J Heart Valve Dis. 1999 Sep;8(5):509-15. Valve
orifice area alone is an insufficient index of aortic stenosis severity: effects of the
proximal and distal geometry on transaortic energy loss.

25 Marcus RH et al., Circulation. 1998 Sep 1;98(9):866-72. Assessment of
small-diameter aortic mechanical prostheses: physiological relevance of the
Doppler gradient, utility of flow augmentation, and limitations of orifice area
estimation.

PD Stein et al., Circulation Research, Vol 39, 58-65, 1976 by American Heart Association. Turbulent blood flow in the ascending aorta of humans with normal and diseased aortic valves.

5 Ku D., Annual Review of Fluid Mechanics Vol. 29: 399-434 (Volume publication date January 1997). Blood flow in arteries.

Weyman AE et al., Rev Cardiovasc Med. 2005;6(1):23-32. Aortic Stenosis: Physics and Physiology—What Do the Numbers Really Mean?

Deac RF et al., Ann Thorac Surg. 1995 Aug;60(2 Suppl):S433-8. New evolution in mitral physiology and surgery: mitral stentless pericardial valve.

10 All of the patents, patent applications, and articles cited herein are incorporated herein by reference.

SUMMARY OF THE INVENTION

Some embodiments of the present invention seek to provide a prosthetic device attachable to an existing valve of a blood vessel, and capable of recovering 15 fluid pressure of flow through the valve and the prosthetic device, as is described more in detail hereinbelow.

There is therefore provided, in accordance with an embodiment of the invention, apparatus including a prosthetic device, having a single flow field therethrough, adapted for implantation in a subject, and shaped so as to define:

20 a fluid inlet, and

a diverging section, distal to the fluid inlet,

the prosthetic device including a plurality of axially-extending struts which extend along at least a portion of the diverging section and diverge 25 outwardly, such that distal ends of the struts are spaced further from one another than proximal ends of the struts throughout a cardiac cycle of the subject, and

the diverging section including a diverging envelope, coupled to the struts, which is adapted to assume an open position thereof during systole, permitting blood flow through the device, and which is adapted to collapse to a closed position thereof during diastole, inhibiting blood flow through the device.

In an embodiment, the apparatus includes a stent, coupled to and surrounding the diverging section.

In an embodiment, the envelope includes a single material, coupled to the struts at respective sites thereof.

5 In an embodiment, the envelope includes a plurality of separate portions, each portion attached to two struts.

In an embodiment, the prosthetic device includes an attachment member, adapted to couple the device to an aortic valve of the subject, such that upon implantation the diverging section is contained within an ascending aorta of the
10 subject.

In an embodiment, the prosthetic device includes attachment members (e.g., clasping members), adapted to engage (e.g., clasp) opposite sides of a native valve of the subject.

In an embodiment, the diverging section widens distally with a widening
15 angle between 0.1° and 50°.

In an embodiment, the diverging section widens distally with a widening angle between 3° and 10°.

In an embodiment, the diverging section widens distally with a widening angle between 5° and 8°.

20 In an embodiment, the prosthetic device is sized for implantation at a native orifice site associated with an aortic valve of the subject, a native diameter of the native orifice not having been enlarged by a physician.

In an embodiment, the prosthetic device is sized for implantation at a native orifice site associated with an aortic valve of the subject, the aortic valve
25 not having been removed.

In an embodiment, the prosthetic device is shaped so as to define a throat section between the fluid inlet and the diverging section.

In an embodiment, the prosthetic device is adapted for implantation in an ascending aorta of the subject, and wherein the diverging section is shaped to

produce pressure recovery, during systole, of blood pressure lost in the throat section.

In an embodiment, the throat section is adapted to be located within an aortic orifice of the subject.

5 In an embodiment, the throat section has an axial length of no more than 20 mm.

In an embodiment, the axial length is between 1 and 10 mm.

In an embodiment, the axial length is approximately 2 mm.

In an embodiment, the axial length is 5 mm.

10 There is provided in accordance with an embodiment of the present invention a prosthetic device including a valve-orifice attachment member attachable to a valve in a blood vessel and including a fluid inlet, and a diverging member that extends from the fluid inlet, the diverging member including a proximal end near the fluid inlet and a distal end distanced from the proximal end, 15 wherein a distal portion of the diverging member has a larger cross-sectional area for fluid flow therethrough than a proximal portion thereof. The diverging member may have a diverging taper that causes fluid to flow therethrough with pressure recovery at the distal end thereof. For example, the taper may widen with a widening angle alpha from 1° to 25° (e.g., about 5°). The fluid inlet may be non- 20 divergent (in the distal direction, e.g., convergent or straight).

An inner envelope may line an inner surface of at least one of the diverging member and the valve-orifice attachment member. The inner envelope may be continuous or may have discontinuities (e.g., openings or slits).

25 The valve-orifice attachment member may include clasping members adapted to clasp opposite sides of the valve near the orifice, for example, an annular clamp adapted to engage valve leaflets.

30 In accordance with an embodiment of the present invention a prosthetic valve may be disposed in the diverging member, the prosthetic valve being adapted to control fluid flow through the diverging member (such as, but not limited to, a mechanical heart valve, biological heart valve, a heart valve allograft,

a vein valve, and/or a pericardial valve). A prosthetic valve may alternatively or additionally be disposed in the fluid inlet section.

Further in accordance with an embodiment of the present invention an annular array of bracing elements may be at the distal end of the diverging member engageable with an inner surface of a blood vessel. A plurality of axially-extending struts may be pivotally mounted near the valve-orifice attachment member and extend through at least a portion of the diverging member.

Further features and advantages of the invention will be apparent from the 10 description below.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

15 Fig. 1A, 1B and 1C are diagrams helpful in explaining the health problem caused by a stenotic valve and the advantages of replacing a stenotic valve orifice by a prosthetic device constructed in accordance with an embodiment of the present invention;

20 Fig. 2 is a diagram illustrating a prosthetic device constructed in accordance with an embodiment of the present invention to treat the above health problem by producing non-turbulent blood flow into the aorta with pressure recovery;

Fig. 3 is a side view of a prosthetic device constructed in accordance with Fig. 2;

25 Fig. 4 is a simplified pictorial illustration of a prosthetic device, constructed and operative in accordance with another embodiment of the present invention;

Fig. 5 a side view of the prosthetic device of Fig. 4;

Fig. 6 is an end view from the heart side illustrating the prosthetic device of Figs. 4 and 5 implanted in the aortic annulus;

Fig. 7 is a perspective view from the aorta side of the implanted prosthetic device of Figs 4 and 5;

Fig. 8 is a fragmentary detail illustrating an example of the manner in which the annular clamps engage the opposite sides of the valve leaflets in the 5 implanted condition of the prosthetic device;

Fig. 9 illustrates a prosthetic device similar to that of Fig. 4 but including braces for bracing the distal end of the prosthetic device when implanted;

Fig. 10 illustrates the prosthetic device of Fig. 9 when implanted in the aortic annulus;

10 Fig. 11 illustrates a cross-section of another construction of a prosthetic device in accordance with an embodiment of the present invention;

15 Figs. 11A-11C illustrate the same kind of prosthetic device with bracing elements as shown in Figs. 9-11, wherein Fig. 11A illustrates the prosthetic device attached to valve leaflets. Fig. 11B illustrates blood flow through the prosthetic device during systole, and Fig. 11C illustrates blood flow through the prosthetic device during diastole;

Fig. 12 is a simplified illustration of yet another prosthetic device constructed in accordance with an embodiment of the present invention;

Fig. 13 is a side view of the device of Fig. 12;

20 Fig. 14 illustrates the prosthetic device of Figs. 12 and 13 in a mid-closed (not completely closed) condition;

Figs. 15A-15H and Figs 16A-16F illustrate a single-sheath method for implanting some types of prosthetic devices in accordance with an embodiment of the present invention;

25 Figs. 17A- 17F illustrate a two-sheath method of implanting a prosthetic device in accordance with an embodiment of the present invention;

Figs. 18A and 18B are simplified pictorial and side-view illustrations of a prosthetic device, constructed and operative in accordance with yet another embodiment of the present invention;

Figs. 19A and 19B are simplified pictorial and side-view illustrations of a prosthetic device, constructed and operative in accordance with still another embodiment of the present invention, and including a valve of biocompatible material attached to an inlet of relatively small diameter, with a diverging 5 pressure-recovering outlet starting approximately where the fully opened valve cusps end; and

Fig. 19C is a simplified illustration of a variation of the prosthetic device of Figs. 19A and 19B, in which the diverging outlet is not connected with the prosthesis in order to allow for a two-staged implantation.

10 DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

Reference is now made to Fig. 2, which diagrammatically illustrates one non-limiting construction of a prosthetic device in accordance with an embodiment of the present invention, and Figs. 1A-1C, which diagrammatically illustrate the manner in which such a prosthetic device may be used for alleviating 15 the work load placed on the heart by an aortic valve suffering from significant aortic stenosis. It is noted that the present invention is not dependent upon any theory or explanation of the manner in which the blood flows in the circulatory system, and any explanation or theory is provided simply for the purposes of elucidation. It is also noted that the embodiments described in detail hereinbelow 20 are only exemplary and the invention is not limited to these specific constructions.

The principles of flow regulation in the cardiovascular system may be similar to those in pipeline systems. Aortic pressure and cardiac output are regulated by the baroreceptor-system with its stretch-receptors in the aorta and proximal aortic artery branches (innominate and carotid arteries). Any loss of 25 pressure may lead to a centrally mediated increase in cardiac output until the preset systemic pressure is again reached.

Fig. 1A diagrammatically illustrates how blood flows from the left ventricle (LV) through the aortic orifice (AO) into the aorta artery (AA). The flow may be affected by a stenotic condition in the aortic orifice AO. Such a stenotic 30 condition effectively reduces the size of the aortic orifice AO to produce a turbulent flow into the aortic artery AA, which produces a substantial loss in

pressure of the blood entering the aortic artery. Such pressure loss is sensed by the baroreceptor system which acts to increase the left ventricular systolic intracavitory pressure, thereby producing increased wall tension in the ventricular chamber, increased myocardial oxygen demand, and ultimately heart failure.

5 As shown in Fig. 1B, when a stenotic valve orifice, as shown in Fig. 1A, is replaced by a prosthetic device of the same throat size but including a Venturi tube configuration, namely one having (in the chosen example) a diverging conical configuration, there is produced a non-turbulent blood flow into the aorta with pressure recovery at the distal (wide) end of the device. The baroreceptor system may therefore not sense a loss of pressure, and may therefore not increase 10 the left ventricular workload in order to compensate for such pressure loss. Accordingly, the replacement of a stenotic valve as shown in Fig. 1A, by a prosthetic device with a diverging (preferably conical) configuration as shown in Fig. 1B, may reduce the workload placed on the left ventricular chamber.

15 Fig. 1C diagrammatically illustrates the difference in the heart load when acting against a stenotic valve as shown in Fig. 1A, and when such a valve is replaced by a prosthetic device having the diverging conical configuration as shown in Fig. 1B. For purposes of example, the diagram of Fig. 1C is based on the following conditions: cardiac output is 5 l/min; the cross-sectional area of the 20 throat is 0.5 cm²; the required pressure gradient is 100 mmHg; and the aortic pressure demanded by the baroreceptors-system in the given example is 125. Thus, the substantial decrease in pressure head loss produced in the stenotic valve 25 (Fig. 1A) may cause the blood pressure in the left ventricle to be 220 mm Hg in systole. However, the addition of a prosthetic device with the same critical area having the diverging conical configuration of Fig. 1B may provide a pressure recovery of 85 mm Hg, and may produce a blood pressure of 140 mm Hg in systole. In essence, pressure head loss may be reduced from 95 to 15 mm Hg.

30 The prosthetic device diagrammatically illustrated in Fig. 2 may include an annular base 2 (also referred to as base section 2 or throat section 2) having a circular cross-section to be implanted in the aortic orifice AO; an annular clamp 3 at its outer end engageable with one face of the valve leaflets (cusps) in the ventricular chamber, and acting as a barrier against regurgitation; and another

annular clamp 4 engageable with the opposite face of the valve leaflets. In this and all other embodiments of the invention, all components of the prosthetic device may be constructed of any suitable medically safe material or combination of such materials, such as but not limited to, metal (e.g., stainless steel, NITINOL and others), or plastic (e.g., nylon, polyurethane and others).

The base section 2 of the prosthetic device may be relatively short, straight, of uniform diameter, and may be located within the aortic orifice. The remainder of the prosthetic device may extend into the aorta artery AA and may be of a diverging (preferably conical) configuration, as shown at 5, in which its 10 diameter gradually increases from its proximal end PE within the heart left ventricle, to its distal end DE within the aorta. The angle of the taper (alpha) of the diverging (preferably conical) section 5 may be determined according to fluid dynamic principles of Venturi flow, such as to produce a non-turbulent blood flow into the aorta, with gradually decreasing velocity and with pressure recovery 15 at the distal end of the prosthetic device.

The diverging section 5 may be straight or curved in any way, concavely or convexly, e.g., parabolic, tulip-shaped, bugle-shaped or otherwise. The distal end of diverging section 5 has a larger cross-sectional area for fluid flow therethrough than the proximal end.

20 Thus, as is well known in fluid dynamics, the flow velocity increases through the small diameter of the base or throat section 2, thereby decreasing the static or lateral pressure; whereas the gradual expansion of the diverging (preferably conical) section 5 decreases the flow velocity, thereby regaining the static or lateral pressure (i.e., producing pressure recovery). Such a construction 25 produces a laminar or non-turbulent flow, reducing or eliminating flow separation in the diverging (preferably conical) section 5, and thereby decreases head losses at the distal end DE of the prosthetic device. The described invention therefore represents a pressure-recovering device, but is not limited to this.

As will be described more particularly below, the prosthetic device may 30 carry a prosthetic valve at its distal end DE. Several commercial prosthetic aortic valve systems are currently available, generally classified as mechanical heart

valves and biological heart valves, respectively (either heart valve allografts, vein valves, or pericardial valves).

In order to accommodate patients of different sizes and weights, the prosthetic device, in its expanded state, may have the following dimensions as shown in Fig. 3: the diameter D1, at the proximal end PE may be within the range of 5–30 mm and typically approximately 14mm; the diameter D2 at the distal end DE may be 10–40 mm and typically approximately 20mm ; the axial length of L1 of the base or throat section 2 may be 0–20 mm and typically approximately 2mm; and the axial length L2 from the proximal end to the distal end may be 5–70 mm and typically approximately 37mm.

In another non-limiting example, a typical diameter D1 of the throat section 2 may be 13-15 mm (covering approximately 2/3 of the average outflow tract diameter of an adult); a typical length L1 may be 5 mm; a typical length (L2-L1) of the diverging conical section 5 may be 18 to 60 mm; and a typical angle alpha (widening angle, deviation from straight segment, that is, half-cone angle) may be from 0.1° to 50°, typically approximately 5-8°, wherein an angle alpha of 5° produces almost full pressure recovery for laminar flow. For example, if the straight throat section 2 has a diameter of 14 mm (cross-sectional area 154 mm²), then a tube attached to this segment and widening with an angle alpha of 5° over a distance of 35 mm may have a diameter of 20 mm at its distal end (cross-sectional area 314 mm²). Consequently, this device may be able to accommodate a 20 mm biological prosthesis at its end (in the aorta) with favorable hemodynamic properties, although the throat size (straight segment within the valve) is only 14 mm in diameter.

25 *The Prosthetic Device of Figs. 4-8*

As indicated earlier, a prosthetic device constructed in accordance with an embodiment of the present invention preferably also includes at the distal end DE of the diverging (preferably conical) section 5, a prosthetic valve to be implanted with the prosthetic device. It is anticipated, however, that for some applications the prosthetic device may be implanted without a prosthetic valve, and the prosthetic valve implanted in a second subsequent operation in the aorta downstream of the prosthetic device.

Figs. 4–8 illustrate a prosthetic device construction of a non-limiting embodiment of the present invention that includes a prosthetic valve.

As shown particularly in the sectional view of Fig. 5, the illustrated prosthetic device includes an expandable body 10 (e.g., constructed of a metal mesh) so as to be transarterially deliverable via a catheter to the implantation site, in this case, the aortic annulus or orifice of an aortic valve affected by aortic stenosis. The illustrated prosthetic device further includes an inner envelope 11, constructed, for example, without limitation, of a biological or flexible polymeric or other biocompatible material, lining the complete inner surface of body 10.

Body 10 and its liner 11 of the illustrated prosthetic device may include a short, straight throat section 12 constructed so as to be implanted in the aortic orifice (AO, Fig. 2). The prosthetic device may further include an annular clamp 13 to engage the face of the valve leaflets (cusps) on one side of the aortic orifice; an annular clamp 14 to engage the face of the valve leaflets on the opposite side of the aortic orifice (in one embodiment only a proximal annular clamp is used); and a diverging (preferably conical) section 15 extending into the aorta artery AA. The construction is such that the diverging (preferably conical) section 15 gradually increases in diameter from the short throat section 12 at the proximal end PE of the prosthetic device to its distal end DE, in order to produce a non-turbulent blood flow through the prosthetic device into the aorta, with pressure recovery at the distal end, as described above with respect to the embodiment of Fig. 2.

It is noted that in one embodiment of the invention, only a proximal annular clamp may be used. Fixation of the device at its distal end may be effected by an aortic wall stent, preferably, but not exclusively, self-expanding.

The distal end of the illustrated prosthetic device may include a prosthetic valve 16. Prosthetic valve 16 may be placed anywhere along the diverging section 15. Preferably, prosthetic valve 16 is a collapsible mechanical or biological valve (e.g. made of a pliable polymeric film) which is effective to open the distal end of the prosthetic device during systole, and to close it during diastole. For example, prosthetic valve 16 may be made of the same material as liner 11 and attached thereto along a zone of attachment, as shown at 17 in Fig. 5.

While a collapsible biological prosthetic valve is preferred, other prosthetic valves systems could be used, such as a ball-cage, a disc-cage, a tilting disc, a bileaflet, a check-valve, etc. In one embodiment a mechanical or synthetic prosthetic valve can be used. Another prosthetic valve which may be used is a 5 pericardial valve, such as the Mitroflow Aortic Pericardial Heart Valve, commercially available from CarboMedics (a Sorin Group company), which has a streamlined sewing cuff intended to optimize heart valve placement for increased blood flow area.

It is further noted that the prosthetic valve 16 may have a diverging shape 10 (e.g., conical) so that the prosthetic valve 16 is the diverging section 15. In other words, there is no need for constructing a diverging section with an additional prosthetic valve therein, rather the prosthetic valve may be the diverging member itself.

In accordance with a non-limiting embodiment of the present invention, in 15 the expanded condition of the illustrated prosthetic device, each of the annular clamps 13 and 14 may include an annular array of clasping members which engage the surfaces of the valve leaflets (cusps) on opposite sides of the aortic annulus, as illustrated more particularly in Figs. 6-8. As illustrated particularly Fig. 8, annular clamp 13 may include an annular array of clasping members 13a 20 engageable with surface 18 (Fig. 6) of the native valve leaflets at the heart left-ventricle side of the aortic annulus AO; and annular clamp 14 may include a similar annular array of clasping members 14a engageable with surface 19 (Fig. 8) of the native valve leaflets at the aorta side of the aortic annulus.

Any suitable method may be used for attaching the inner envelope or liner 25 11 to the inner surface of diverging section 10. Non-limiting examples include: adhesive bonding, e.g., by using a long-lasting biocompatible adhesive; ultrasonic welding, e.g., using sonic energy to soften the plastic envelope 11 where it contacts the diverging section 15; or injection-molding the polymeric material to embed the diverging section 15 therein. Other possible methods include a 30 mechanical locking arrangement wherein the inner envelope is mechanically locked to the diverging section 15, or a suturing technique wherein the inner envelope is sutured to the diverging section 15.

As mentioned hereinabove, all components of the prosthetic device may be constructed of any suitable medically safe material or combination of such materials, such as but not limited to, metal (e.g., stainless steel, NITINOL and others), or plastic (e.g., nylon, polyurethane and others). Without limitation, liner 5 11 may be made of a suitable biocompatible polymeric or plastic material, or biological material (e.g. pericard).

Examples of metals that may be used are tungsten, platinum, and titanium. Metal alloys possessing the required physical properties include (but are not limited to) Stainless Steel 316 and NITINOL (nickel titanium), both of which are 10 biocompatible and commercially available. For example NITINOL may be used for the annular clamps 13 and 14, and the diverging conical section 5, while another conventional metallic stent material, such as Stainless Steel 316, may be used for the base or throat section 12. Dacron is typically used for covering NITINOL-based devices, but other suitable biocompatible polymeric or 15 elastomeric materials can be used for the inner envelope or liner 11.

The Prosthetic Devices of Figs. 9, 10 and Fig. 11 (and Figs. 11A-11C)

Fig. 9 illustrates a prosthetic device similar to that described above with respect to Figs. 4-8, and therefore to facilitate understanding, corresponding parts have been identified by the same reference numerals. The main difference in the 20 prosthetic device illustrated in Fig. 9 is the provision of a plurality of bracing elements 20 carried by the distal end DE of the body 10 and engageable with the inner surface of the aorta for bracing the prosthetic device, particularly its distal end, within the aorta as shown in Fig. 10.

In Fig. 11, clasping members 34a of an annular clamp 34 may engage the 25 distal (aorta) side of the valve leaflets in the aortic annulus. Bracing elements, generally designated 40, may comprise an annular array extending from the distal (broad) end of the prosthetic device, including connection elements 41. A diverging (preferably conical) section 35 extends from clasping members 34a to bracing elements 40. Clasping members 34a cooperate with clasping members 33a 30 carried by a throat section 32 to clamp the device in the aortic orifice. Bracing elements 40 are configured so as to engage the inner surface of the aorta, preferably adjacent to, the distal end of the prosthetic device, in order to brace that

end when the prosthetic device is implanted in the aortic annulus. They may be configured so as not to obstruct or occlude the coronary arteries adjacent to the aortic annulus (as described below with reference to Fig. 16F).

For simplification purposes, Fig. 11 omits the inner liner and the prosthetic 5 valve, e.g. 11 and 16, respectively, shown in Fig. 5.

Figs. 11A-11C illustrate the same kind of prosthetic device with bracing elements as shown in Figs. 9-11. Fig. 11A illustrates the prosthetic device attached to valve leaflets (e.g., in the aortic annulus). Fig. 11B illustrates blood flow through the prosthetic device during systole. The blood flows through the 10 diverging member of the prosthetic device in non-turbulent flow, and there is pressure recovery at the distal end of the diverging member. Fig. 11C illustrates blood flow through the prosthetic device during diastole. It is seen that the prosthetic device prevents the blood from flowing back through the valve orifice.

The Prosthetic Device of Figs. 12-14

15 Figs. 12-14 illustrate a prosthetic device that may include a base 110 and an envelope 111, which may also serve as a prosthetic valve. During systole, the envelope 111 opens and assumes a diverging conical configuration so as to produce the non-turbulent blood flow into the aorta with pressure recovery at the distal end of the envelope; whereas during diastole, envelope 111 collapses to 20 inhibit (i.e., substantially block or completely block) the flow therethrough. It is noted that the prosthetic device shown in Figs. 12-14 (like prosthetic devices shown in others of the figures) has a single blood flow field therethrough. In other words, blood entering the device remains within a common field within the device, until the blood leaves the device.

25 Base 110, which corresponds to the throat section (e.g., 12, Fig. 5) of the prosthetic device to be implanted into the aortic annulus, further includes two annular arrays of clasping members 113 and 114, on its opposite sides for engaging the opposite faces of the valve leaflets within the aortic annulus, which correspond to annular clamps 13, 14, of Fig. 5.

30 Envelope 111 lines the inner surface of base 110. It then extends outwardly of base 110 to define the diverging (preferably conical) section of the

prosthetic device, and also a prosthetic valve carried by the distal end of the prosthetic device (corresponding to sections 15 and valve 16, respectively, in Fig. 5).

Envelope 111 may further include a plurality of axially-extending struts 112 pivotally mounted at 112a to base 110, to permit the envelope to expand, during systole, to its open-valve condition to permit blood therethrough, while at the same time assuming the diverging conical configuration for producing non-turbulent blood flow into the aorta with pressure recovery at the distal end. Struts 112 also permit envelope 111 to collapse during diastole in order to effectively 10 block the blood flow therethrough, and thereby to perform the function of a prosthetic valve. Fig. 14 illustrates envelope 111 in a partially collapsed condition. It is noted that struts 112 are typically in a diverging configuration throughout all stages of the cardiac cycle (including diastole, as shown in Fig. 14).

Reinforcing struts 112 may be constructed of the same material as base 15 110 and may be pivotally mounted to the base by integrally-formed hinges. Alternatively, reinforcing struts 112 may be of a different material, e.g., of a different metal or plastic, sufficiently stiff to support envelope 111 in its valve-open conical configuration during systole, and mechanically hinged to base 110 in any suitable manner.

20 It will thus be seen that the prosthetic device illustrated in Figs. 12–14 not only acts to regulate the flow from the left ventricle into the aorta to produce the above-described non-turbulent flow into the aorta with pressure recovery, but also serves as a prosthetic valve which opens during systole and closes during diastole.

25 In the configuration shown in Fig. 13, as described above, the envelope 111 may open and close as a prosthetic valve. In other words, the diverging section of the prosthetic device may itself serve as the prosthetic valve that opens in systole and closes in diastole, without any need for placing a prosthetic valve 30 somewhere in the diverging section (as shown and described in other embodiments).

Alternatively, instead of constructing the diverging section with the pivoting reinforcing struts 112, the diverging section may be the prosthetic valve itself, as described above with reference to the embodiment of Figs. 4-8.

MODES OF DEPLOYMENT

5 As indicated above, the prosthetic device of an embodiment of the present invention may be implanted in an orifice formed in a wall of a body passageway. It is therefore constructed to have a compressed state for delivery via the body passageway to the implantation site and to be expandable at the implantation site to an expanded state for implantation into the orifice. The embodiments of the 10 invention described above are intended for implantation in the aortic annulus of a patient's heart, and therefore are constructed for transarterial delivery to the aortic annulus and expansion at the aortic annulus for implantation therein.

15 A single-sheath mode of deployment is described below with respect to Figs. 15A-15H and 16A-16h; and a two-sheath mode of deployment is described below with respect to Figs. 17A-17h.

Single-Sheath Mode of Deployment

20 Figs. 15A-15H diagrammatically illustrate a method of deploying the prosthetic device, e.g., of Fig. 2, using a single sheath; whereas Figs. 16A-16F illustrate that method used for deploying a prosthetic device of the construction illustrated in Fig. 11, i.e., including an annular array of bracing elements 40.

25 In the single-sheath method illustrated in Figs. 15A-15H, the prosthetic device, generally designated PD and of the construction illustrated in Fig. 2, is to be implanted into the aortic orifice AO of the aortic valve AV by means of the annular clamps 3, 4. When so implanted, the throat section 2 of the prosthetic device is implanted in the aortic orifice AO, and the diverging conical section 5 of the prosthetic device is received within the aortic artery AA.

30 In order to deliver the prosthetic device PD to the implantation site, it may be introduced into a catheter 200 which may include a balloon 201 and a sheath 202 for post implantation dilations. Balloon 201, in its deflated condition, receives the throat section 2 and the two annular clamps 3, 4 of the prosthetic device. Sheath 202 encloses the complete prosthetic device and retains it including its

annular clamps 13, 14 and diverging conical section 15, in a compressed state for transarterial delivery. The device may also be introduced after performing balloon pre-dilation (balloon valvuloplasty), in which case the device insertion (implantation) catheter will not include a balloon.

5 The catheter may be introduced into a peripheral artery of the patient and manipulated in a conventional manner to bring the throat section 2 into alignment with the aortic orifice AO, with the two annular clamps 3, 4, located on opposite sides of the valve leaflets defining the orifice (Fig. 15A).

Sheath 202 is then moved to one side (Fig. 15B) to release, for expansion, 10 first annular clamp 3 (Fig. 15C), then annular clamp 4 (Figs. 15D, 15E), and finally the diverging conical section 5 of the prosthetic device (Fig. 15F). Balloon 201 is then inflated (Fig. 15G) to firmly press the base section 2 within the orifice, and then deflated (Fig. 15H) to permit the catheter 200, together with the balloon 201 and sheath 202, to be removed from the artery, leaving the prosthetic device 15 clamped within the orifice.

Since the prosthetic device is clamped with the orifice by the two annular clamps 3, 4, it may not be essential use a balloon; nonetheless this may be done to better assure proper implantation of the prosthetic device within the orifice. However, the provision of the two annular clamps 3, 4 enables the throat section 2 20 to be expanded only slightly, i.e., to a much lesser extent than in a conventional stent-type implantation, and thereby reduces the risk of obstructing or occluding the coronary arteries.

Figs. 16A–16F illustrate the above-described one-sheath method of deploying the prosthetic device illustrated in Fig. 11 (i.e., including the annular 25 array of bracing elements 40) through the following conditions: Fig. 16A, wherein the throat section 32 is located within the aortic orifice; Fig. 16B, wherein the sheath 201 has been moved to one side sufficient to release the clasping members 33a of clamp 33; Fig. 16C, wherein continued movement of the sheath releases the clasping members 34a of the other annular clamp 34; Figs. 16D and 16E, wherein 30 continued movement of the sheath starts to release the diverging section 35 of the prosthetic device; and Fig. 16F, wherein the sheath has been moved sufficiently to release for expansion the complete prosthetic device, including the diverging

section 35 and the bracing elements 40 around the diverging section 35. As shown particularly in Fig. 16F, the bracing elements 40 may be configured so as not to obstruct the coronary arteries CA in the implanted condition of the prosthetic device.

5 While the method as illustrated in Figs. 16A–16h does not use an inflatable balloon, it will be appreciated that such an inflatable balloon could also be used, as described above with respect to Figs. 15A–15H, to better assure firm implantation of the prosthetic device in the aortic orifice.

Two-Sheath Mode of Deployment

10 Figs. 17A–17h illustrate a two-sheath method of deployment of the prosthetic device. For purposes of example, this prosthetic device is that illustrated as Figs. 4–8 described below.

15 In the two-sheath method, the catheter, therein designated 300, includes a first sheath 301 at the outer end to engage annular clamp 13 of the prosthetic device, and a second sheath 302 extending inwardly from sheath 301 so as to engage annular clamp 14 and the diverging conical section 15 of the prosthetic device. This is the condition illustrated in Fig. 17A.

20 The catheter is first manipulated to locate throat section 12 of the prosthetic device in the aortic orifice (Fig. 17A). Sheath 302 is then moved laterally to one side (rightwardly in the sense of the drawing) in order to release annular clamp 14 (Fig. 17B). When that clamp has been released, the catheter is then moved inwardly of the heart (leftwardly) a slight amount (Fig. 17C) to firmly bring clasping members 14a of annular clamp 14 against the respective face of the valve leaflets, such that annular clamp 14 firmly engages the aorta face (18, Fig. 25 8) of the valve leaflets as shown in Fig. 17C.

Outer sheath 301 is then moved away from sheath 302, i.e., leftwardly, further into the heart. This releases annular clamp 13 to its expanded state into contact with the surface (19, Fig. 8) of the valve leaflets facing the heart left-ventricle (Fig. 17D). At this time the catheter 300 may then be moved in the 30 opposite direction (rightwardly) to firmly engage clasping members 13a of annular clamp 13 with that surface of the valve leaflet.

Sheath 302 within the aorta may then be moved further away from sheath 301, to thereby release the remainder of the prosthetic device for expansion, as shown in Figs. 17E and 17F.

The catheter illustrated in Figs. 17A–17F may also include a balloon (not 5 shown) if desired, so as to slightly further expand base 12 within the aortic orifice, in which case the balloon would then be deflated in order to permit removal of the catheter and its sheaths.

It will be appreciated that in the above described deployment methods, even if no balloon is used, the base section of the respective prosthetic device will 10 still expand slightly when the respective sheath or sheaths are removed, to firmly seat the base section within the aortic annulus and also to permit removal of the catheter and its sheath or sheaves. However, providing such a balloon permits an additional expansion of the base section of the prosthetic device sufficient to better assure firm implantation within the orifice, but not to the extent of 15 obstructing or occluding the coronary arteries.

Reference is now made to Figs. 18A and 18B, which illustrate a prosthetic device 80, constructed and operative in accordance with yet another embodiment of the present invention. Prosthetic device 80 may be constructed similarly to prosthetic device 10 of Fig. 4, with like elements being designated by like 20 numerals. Prosthetic device 80 may include a proximal attachment appliance 82 (on the ventricular or inlet side of the device), which may consist of an array of clasping elements 84 covered by a liner 86 bent in order to extend to and cover the walls which form the left ventricular outflow tract (basal ventricular septum, basal portion of the anterior mitral leaflet). The proximal attachment appliance 82 and 25 liner 86 may have a horn shape with the proximal end of the horn being wider than the distal end of the horn (near the clasping elements 84). This shape may create a ventricular inlet in form of a covered wall stent (or wall-stent like) with radial forces acting to stabilize the device by pressing its inlet against the ventricular septum and the basal anterior leaflet. This inlet may be symmetric, or 30 asymmetric, i.e. extending over a shorter segment of the anterior leaflet, so as not to compromise mitral valve competence..

Reference is now made to Figs. 19A and 19B, which illustrate a prosthetic device 90, constructed and operative in accordance with yet another embodiment of the present invention. Prosthetic device 80 may be constructed similarly to prosthetic device 10 of Fig. 4, with like elements being designated by like numerals. In prosthetic device 90, a valve 16 of biocompatible material attached to an inlet 92 of relatively small diameter (typically, but not exclusively 12 to 16 mm), will be implanted into the native valve, with a diverging pressure-recovering outlet 94 starting approximately where the fully opened valve cusps end. Thus, the fully opened valve may in systole form a straight segment (the length of which is given by the valve's cusp) and in continuation of the inlet direct blood flow into the diverging pressure-recovering outlet. In diastole, valve closure will create a space between the valve prosthesis and the diverging outlet, roughly given by the length of the cusps, thus allowing blood supply of the coronaries through the proximal (upstream) end of the diverging outlet. In one embodiment the distal diverging outlet 94 may be connected via ribs, struts, or other connecting structure 96 to the valve prosthesis (e.g., the inlet 92 holding the cusps). In another embodiment, seen in Fig. 19C, the diverging outlet 94 may not be connected with the prosthesis (e.g., not connected to inlet 92) in order to allow for a two-staged implantation (either the diverging outlet first and the prosthesis through the already deployed outlet, or vice versa). In this configuration the diverging outlet may be covered up to its distal (downstream) end that extends to the aortic walls in the manner of a wall-stent, or, the liner may end before the aortic wall is reached, thus allowing for coronary blood supply through a passage between aortic wall and diverging outlet.

In another embodiment the pressure recovering device may be deployed above the native valve, with the native valve left in place. The pressure recovering device may have an internal covered shape which forms a diverging diffuser. The internal shape may have a converging section or a straight section (constant area). It may be placed above the narrowed aortic valve orifice in order to engage the exiting high-velocity jet before kinetic energy dissipation takes place, leading to early reattachment of the streamlines of flow to the liner covering the device. The diverging shape of the device's outlet may then enable gradual expansions of the

streamlines of flow, allowing flow velocity to decrease gradually without energy dissipation and kinetic energy to be reconverted into lateral pressure (pressure recovery). The proximal (upstream) end may start above the coronary arteries, preferably, but not exclusively, at the sinotubular junction; in this embodiment 5 coronary blood supply occurs in the same manner, as before the implantation of the device, while the device serves as an aortic endoprosthesis reshaping the lumen of the aorta so as to allow pressure recovery. In another embodiment the proximal (upstream) end of the device starts at or immediately above the native valve in a subcoronary position, while coronary blood flow is provided through 10 the space left between the end of the liner at the distal (downstream) end of the diverging outlet and its attachment to the aortic wall in a wall stent-like manner.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both 15 combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

CLAIMS

1. Apparatus comprising a prosthetic device, having a single flow field therethrough, adapted for implantation in a subject, and shaped so as to define:
 - a fluid inlet, and
 - 5 a diverging section, distal to the fluid inlet, the prosthetic device comprising a plurality of axially-extending struts which extend along at least a portion of the diverging section and diverge outwardly, such that distal ends of the struts are spaced further from one another than proximal ends of the struts throughout a cardiac cycle of the subject, and
 - 10 the diverging section comprising a diverging envelope, coupled to the struts, which is adapted to assume an open position thereof during systole, permitting blood flow through the device, and which is adapted to collapse to a closed position thereof during diastole, inhibiting blood flow through the device.
2. The apparatus according to claim 1, comprising a stent, coupled to and 15 surrounding the diverging section.
3. The apparatus according to claim 1, wherein the envelope comprises a single material, coupled to the struts at respective sites thereof.
4. The apparatus according to claim 1, wherein the envelope comprises a plurality of separate portions, each portion attached to two struts.
- 20 5. The apparatus according to claim 1, wherein the prosthetic device comprises an attachment member, adapted to couple the device to an aortic valve of the subject, such that upon implantation the diverging section is contained within an ascending aorta of the subject.
6. The apparatus according to claim 1, wherein the prosthetic device 25 comprises attachment members, adapted to engage opposite sides of a native valve of the subject.
7. The apparatus according to claim 1, wherein the diverging section widens distally with a widening angle between 0.1° and 50°.
8. The apparatus according to claim 1, wherein the diverging section widens 30 distally with a widening angle between 3° and 10°.

9. The apparatus according to claim 1, wherein the diverging section widens distally with a widening angle between 5° and 8°.
10. The apparatus according to claim 1, wherein the prosthetic device is sized for implantation at a native orifice site associated with an aortic valve of the subject, a native diameter of the native orifice not having been enlarged by a physician.
11. The apparatus according to claim 1, wherein the prosthetic device is sized for implantation at a native orifice site associated with an aortic valve of the subject, the aortic valve not having been removed.
- 10 12. The apparatus according to any one of claims 1-11, wherein the prosthetic device is shaped so as to define a throat section between the fluid inlet and the diverging section.
13. The apparatus according to claim 12, wherein the prosthetic device is adapted for implantation in an ascending aorta of the subject, and wherein the diverging section is shaped to produce pressure recovery, during systole, of blood pressure lost in the throat section.
14. The apparatus according to claim 12, wherein the throat section is adapted to be located within an aortic orifice of the subject.
15. The apparatus according to claim 12, wherein the throat section has an axial length of no more than 20 mm.
16. The apparatus according to claim 15, wherein the axial length is between 1 and 10 mm.
17. The apparatus according to claim 15, wherein the axial length is approximately 2 mm.
- 25 18. The apparatus according to claim 15, wherein the axial length is 5 mm.

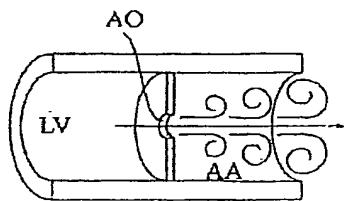


FIG.1a

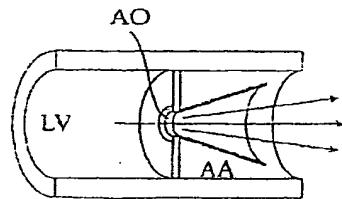


FIG.1b

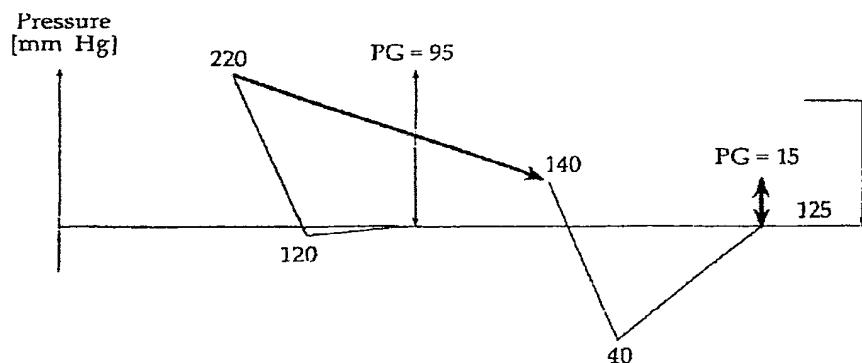


FIG.1c

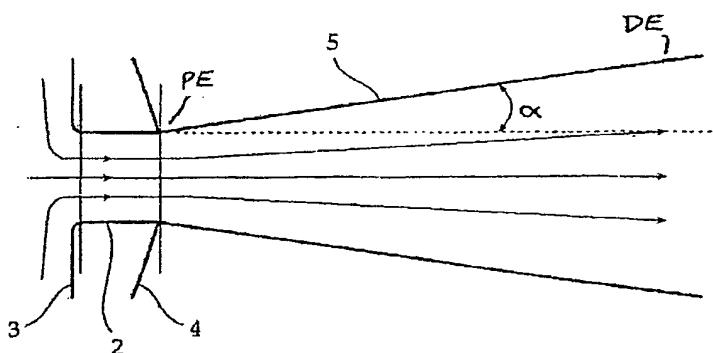


FIG.2

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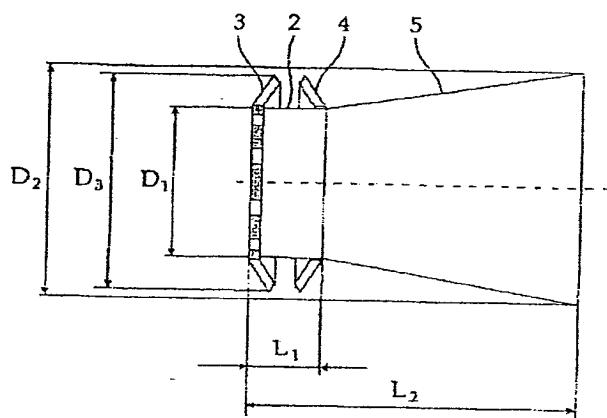


FIG.3

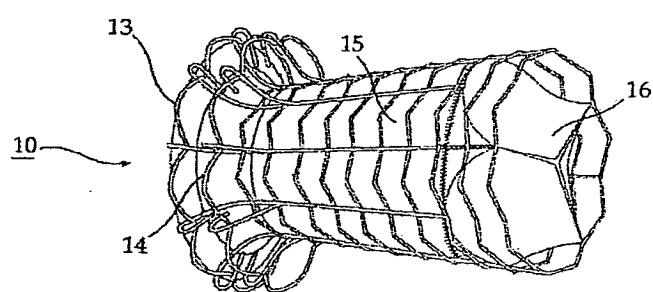


FIG.4

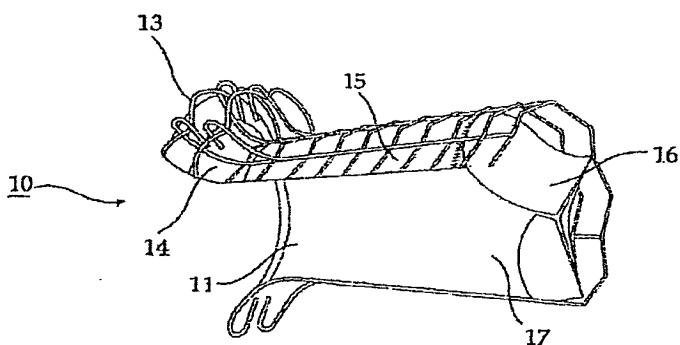


FIG.5

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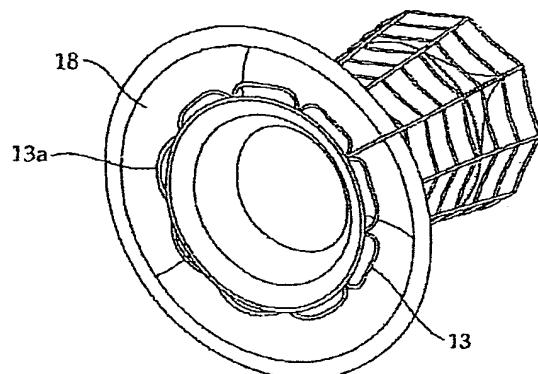


FIG.6

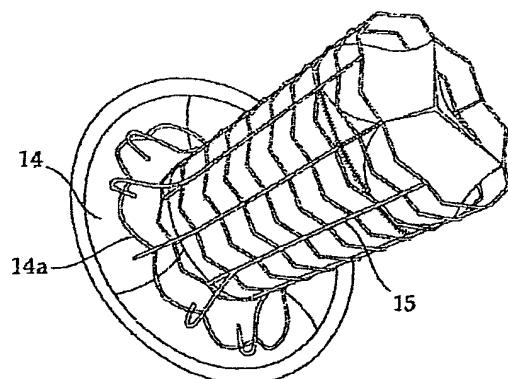


FIG.7

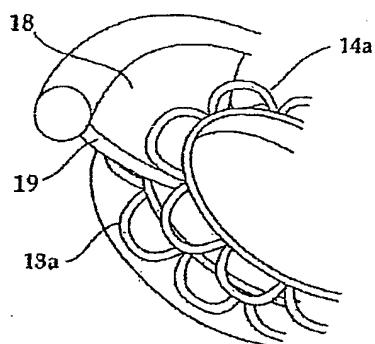


FIG.8

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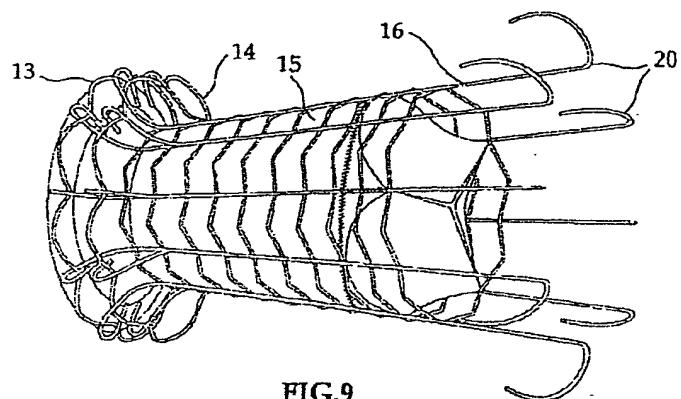


FIG.9

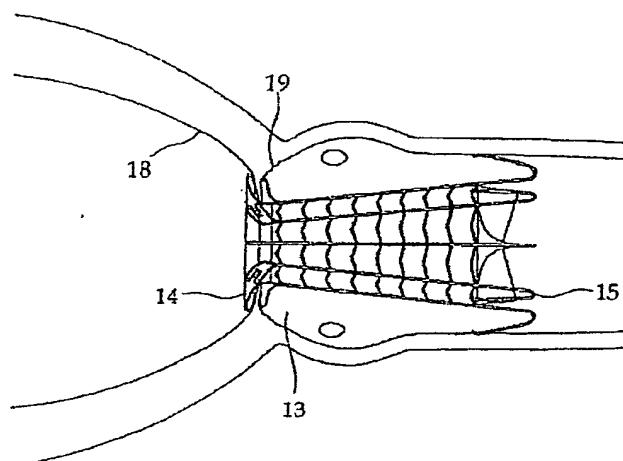


FIG.10

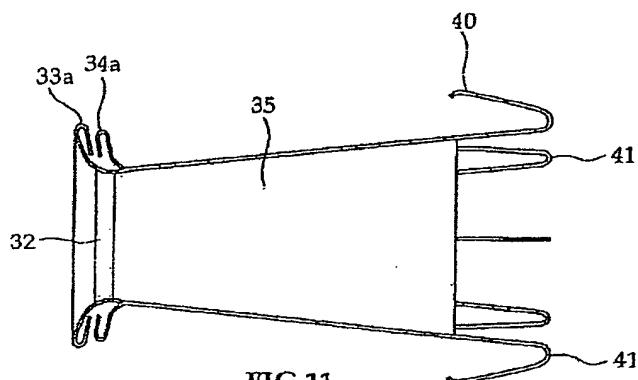


FIG.11

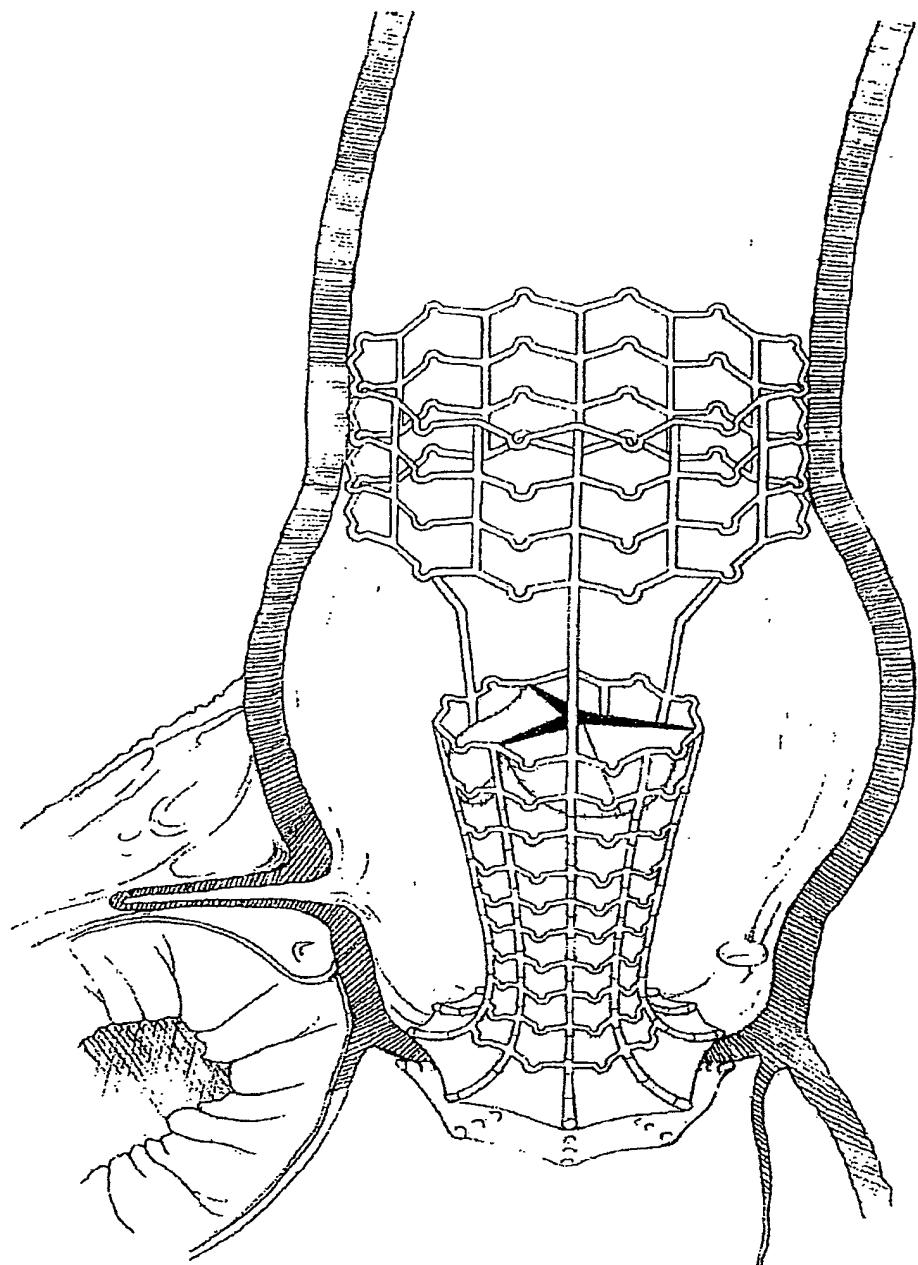
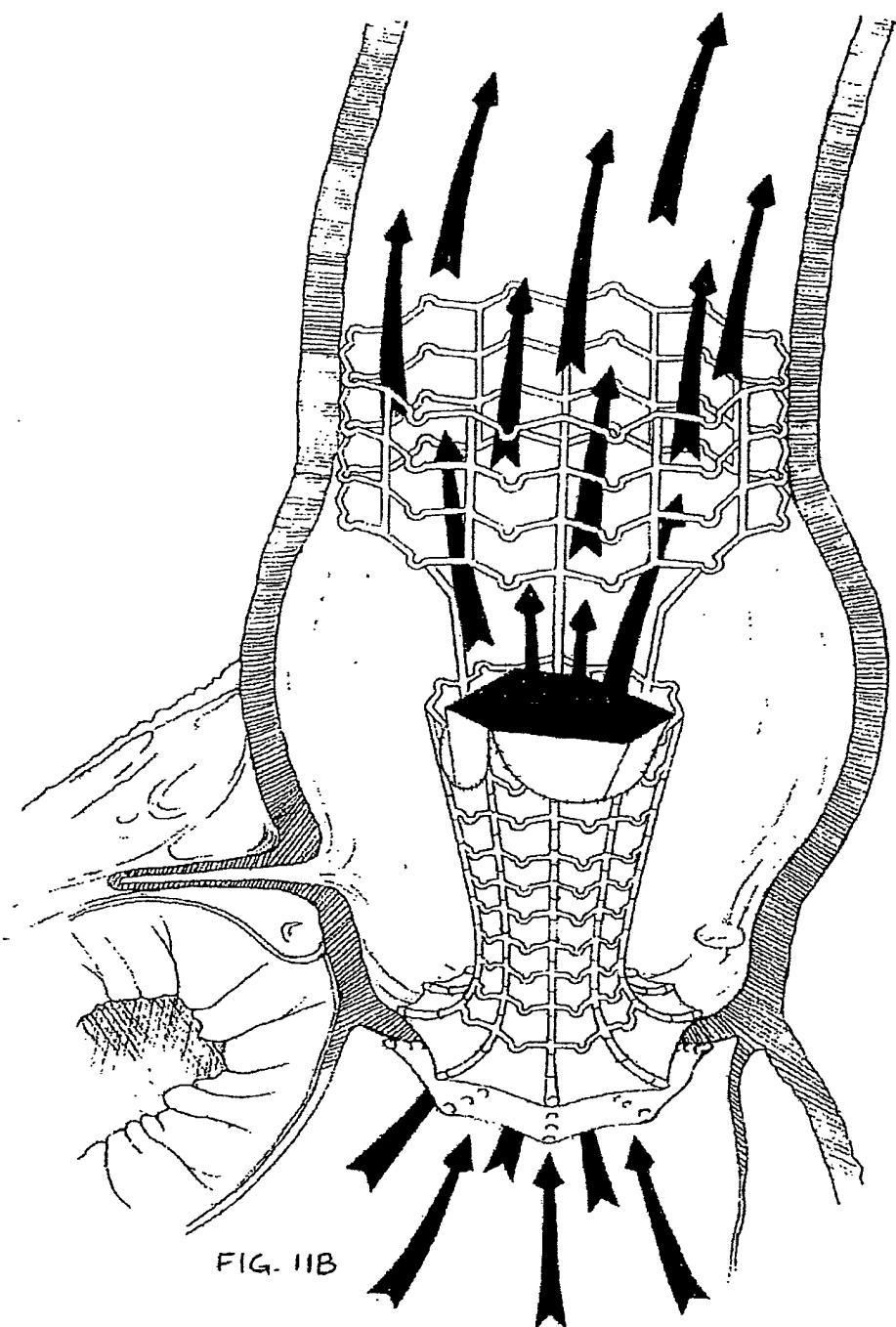
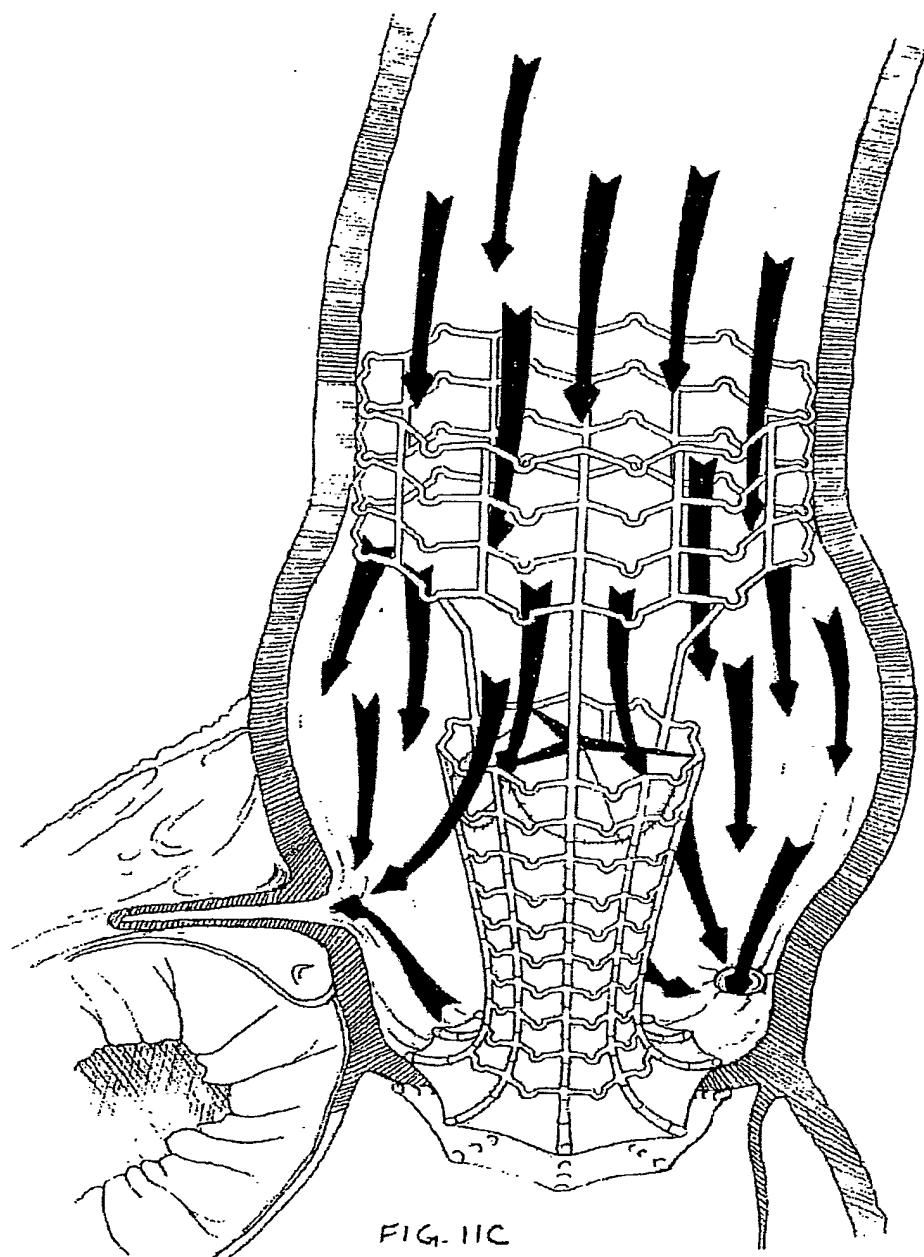


FIG. 11A





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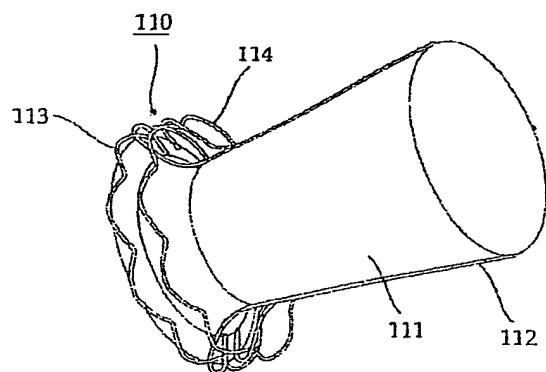


FIG.12

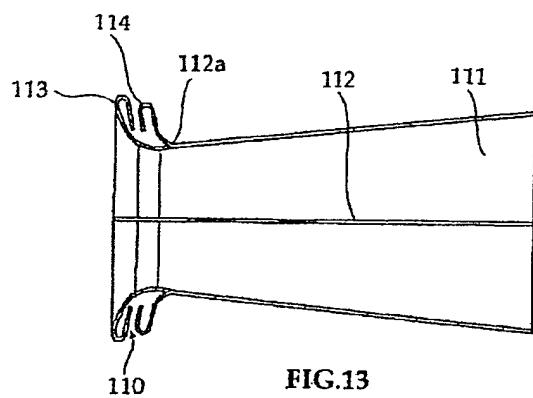


FIG.13

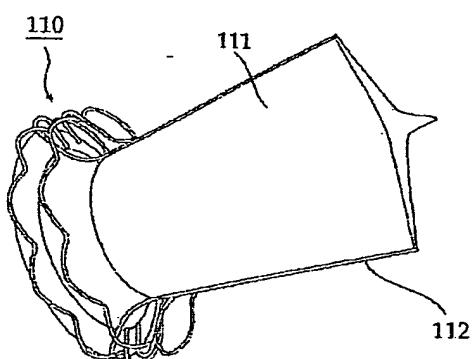


FIG.14

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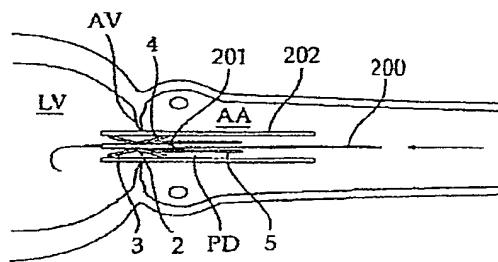


FIG.15a

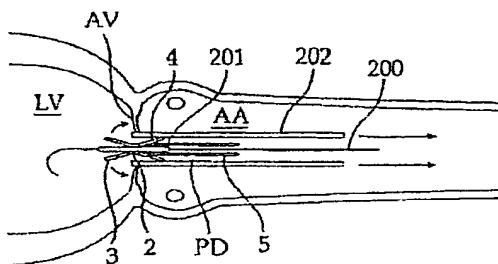


FIG.15b

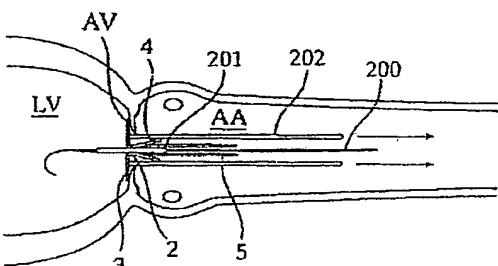


FIG.15c

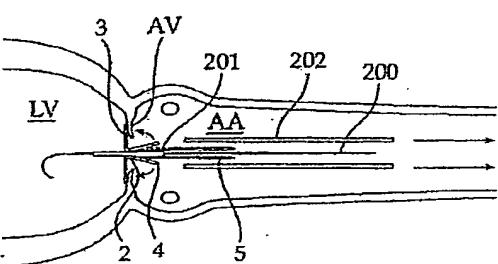


FIG.15d

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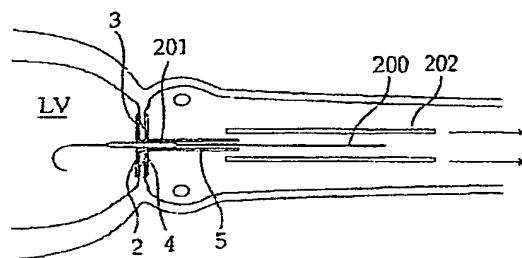


FIG.15e

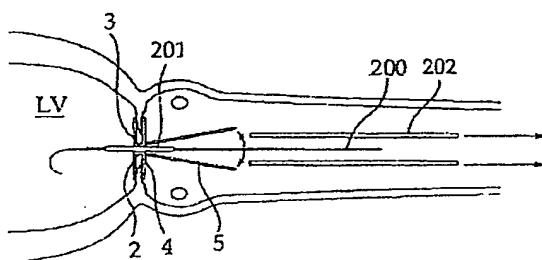


FIG.15f

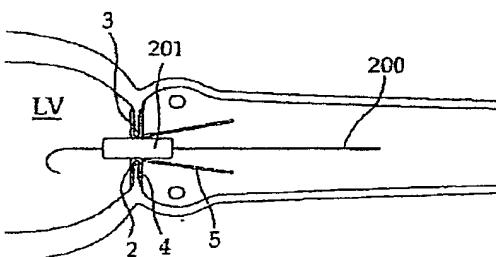


FIG.15g

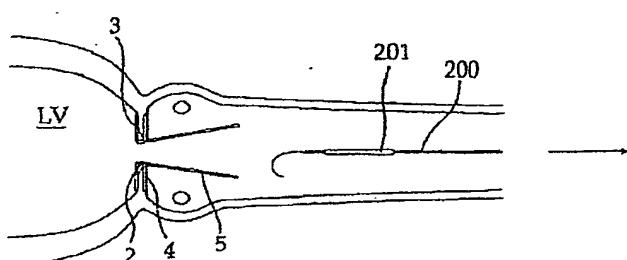


FIG.15h

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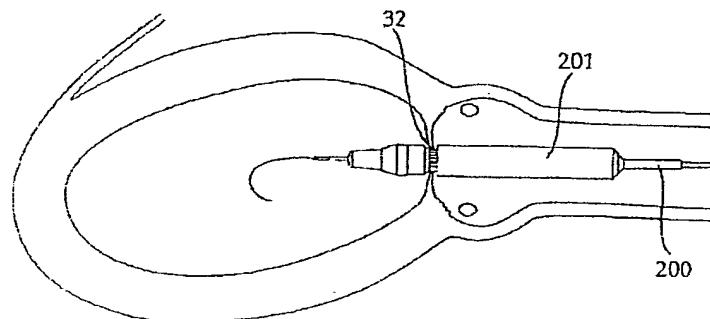


FIG.16a

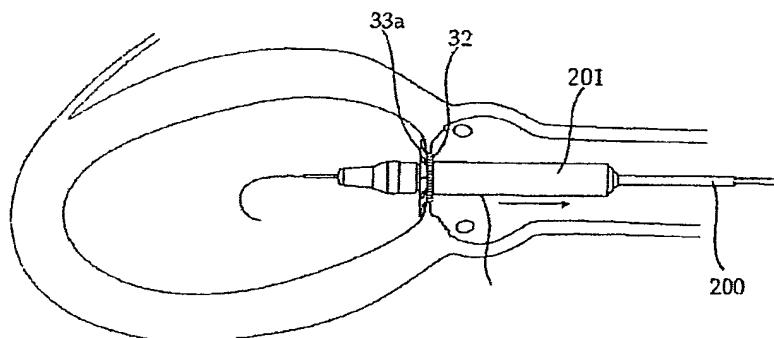


FIG.16b

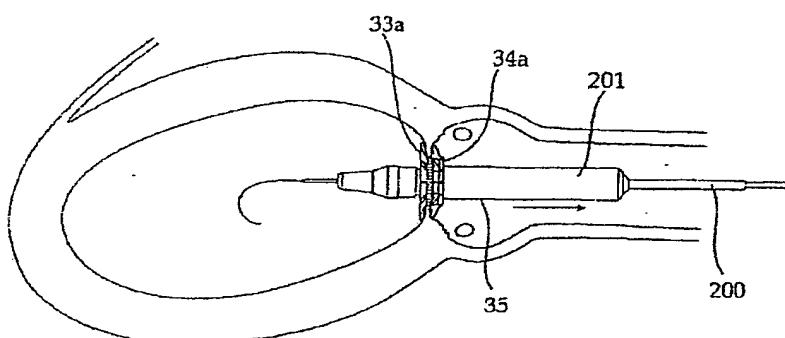


FIG.16c

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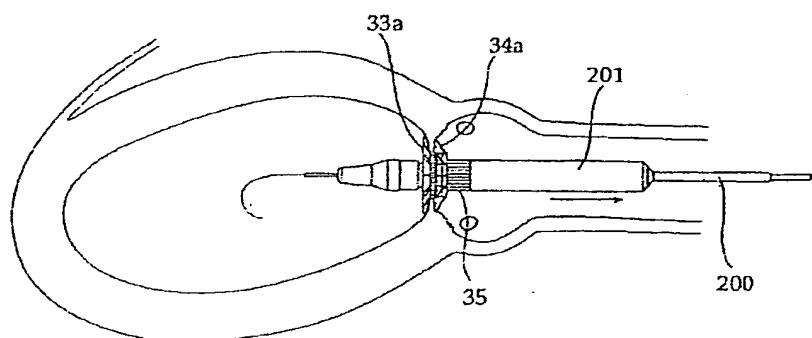


FIG.16d

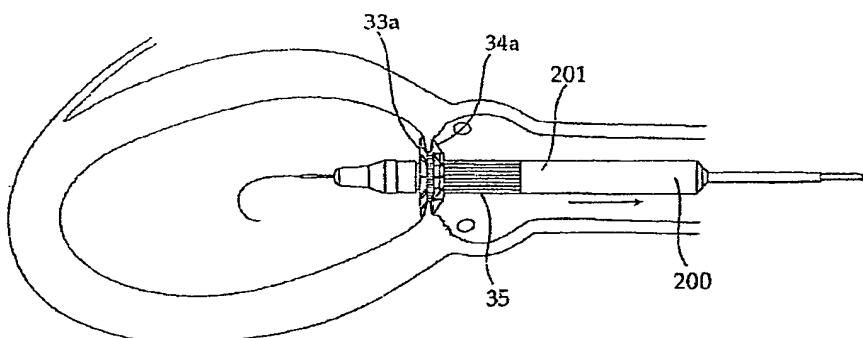


FIG.16e

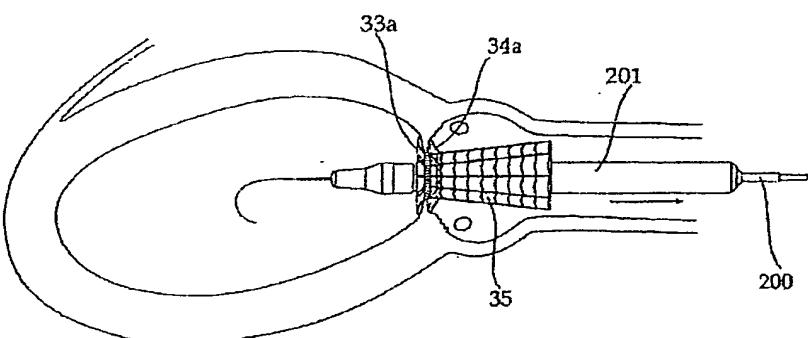


FIG.16f

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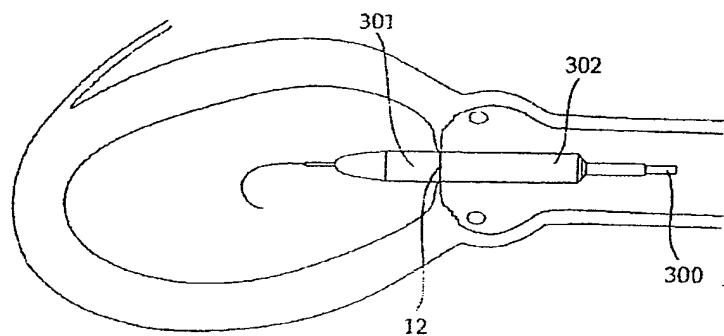


FIG.17a

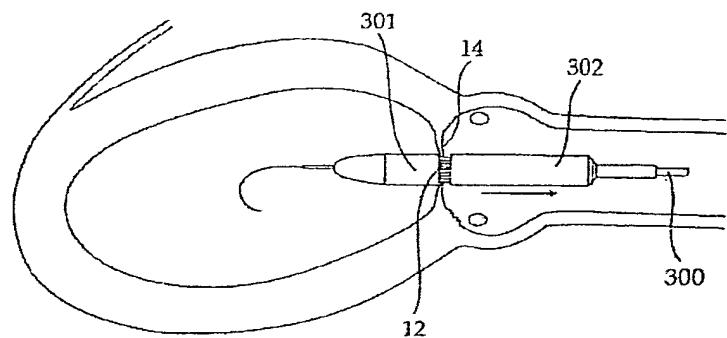


FIG.17b

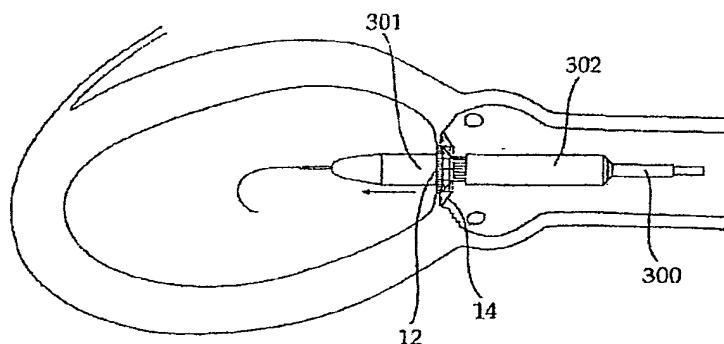


FIG.17c

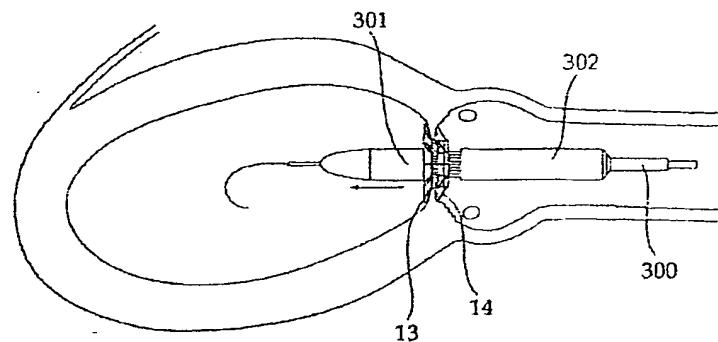


FIG.17d

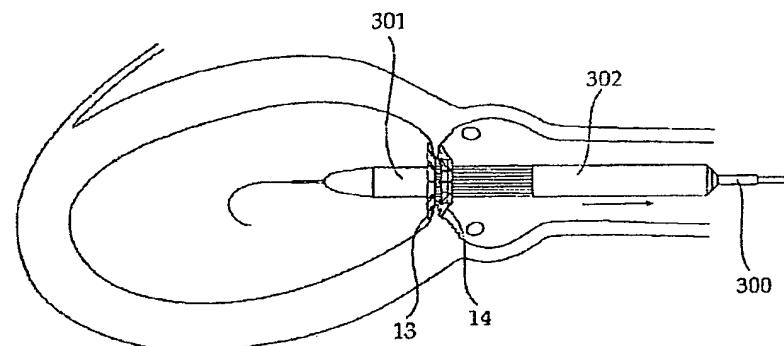


FIG.17e

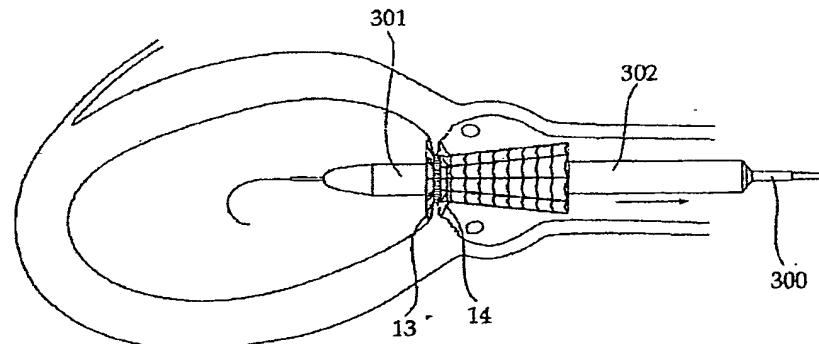


FIG.17f

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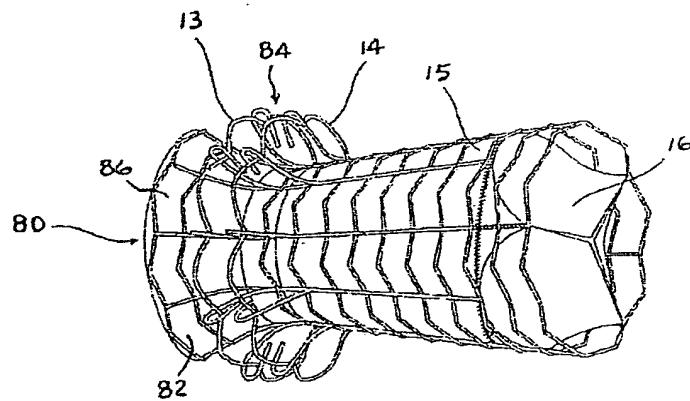


FIG.18a

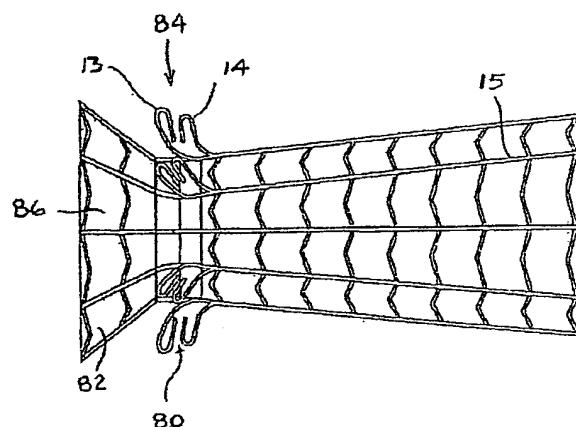


FIG.18b

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